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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,039	01/22/2004	Temple Smith	2003320-0036 (Alien Seque	6987
24280	7590	06/02/2006	EXAMINER	
CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/763,039

Applicant(s)

SMITH ET AL.

Examiner

Jeanine A. Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/7/05; 11/16/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 2/06; 5/06</u> .                   |

### **DETAILED ACTION**

1. This action is in response to the papers filed May 9, 2006. Currently, claims 1-3 are pending.

### ***Election/Restrictions***

2. Applicant's election without traverse of Group I, Claims 1-3 in the paper filed May 9, 2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

### ***Priority***

3. This application claims priority to provisional application 60/441,832, filed January 22, 2003.

### ***Drawings***

4. The drawings are objected to. The drawings contain sequences which are not identified by SEQ ID NO:. Appropriate correction is required.

### ***Sequence Rules***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

For example, the figures contain many sequences which are not identified by SEQ ID NO:.

For example, pages 37 and 39 further contains a sequence which is not identified by SEQ ID NO:.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2 rejected under 35 U.S.C. 102(b) as being anticipated by Schena et al. (PNAS, Vol. 93, pages 10614-10619, October 1996).

Schena teaches parallel human genome analysis: microarray-based expression monitoring using human cDNAs on an array. The array comprises cDNAs from human clones and Arabidopsis controls. The array is a solid support of a microscope slide and a plurality of nucleic acid probes. Therefore, Schena teaches a solid support comprising a plurality of probes including an alien probe (Arabidopsis) that is not normally present in human cDNA samples. Alternatively the alien probe may be the

human cDNA which are not normally present in Arabidopsis samples. Thus, Schena anticipates every limitation of the instant claims.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al. (US Pat. 6,251,601, June 2001).

Bao teaches simultaneous measurement of gene expression and genomic abnormalities using nucleic acid microarrays. The microarray of Bao is comprised of spots with genomic DNA from 31 human putative amplified gene loci, one spot of total human genomic DNA, three control spots of pooled genomic DNA, each spot a pool of equal amounts of genomic DNA for ten of these oncogene loci, and one spot of lambda phage DNA (col. 25, lines 40-46). The microarray thus comprises a plurality of locations (i.e. nearly 35 features). The lambda phage DNA is alien to a human cDNA sample. Therefore, Bao teaches every limitation of the instant claims.

8. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Shah (US Pat. 6,916,621, July 2005).

Shah teaches a method for array-based comparative binding assays. Shah teaches an array comprising immobilized calibration molecules (i.e. nucleic acids) (abstract). The methods comprise determining the amount of a calibration molecule wherein a known amount of a calibration molecule is spotted on each array. The average copy number of a calibration sequence is determined when a known amount of calibration sequence is mixed with the first and second samples (col. 6, lines 50-55).

Shah teaches the calibration sequence which is mixed with the first and second samples is derived from a different source from which the sample nucleic acids were derived. Moreover, Shah teaches that sequences from a genome other than that in one of the sample (such as *Drosophila*) are used as a calibration sequence to prevent crossover hybridization from the genome being tested.

9. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Kincaid (2003/0186310, October 2003).

Kincaid teaches an apparatus of detecting features on a microarray. The apparatus comprises a control probe at each feature location on the microarray (abstract). The test probe is attached to each feature of the microarray such that each feature comprises a control probe and a test probe (abstract). As seen in the flow diagram of Figure 1, the control probe and test probe are attached to the support. The added labeled control probe and the test target are hybridized and the microarray is scanned. Control probes (i.e. alien sequences) are a specific, known sequence of nucleic acids in known quantity that do not interfere with a hybridization assay of a target sample under test (para 16). Moreover the control sequences are statistically known not to hybridize or otherwise interfere with an oligomer test probe or target sample under test (para 55). The control probe does not function as an oligomer test probe and does not hybridize with a test target sample and does not interfere with hybridization (para 55). Kincaid teaches the control probes do not take up "valuable real estate" or dedicated features on the microarray but instead the control probe is

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populated on each feature of the microarray along with a respective oligomer test probe (para 16). The control probe also allows detection of all feature locations regardless of the quality of the signal from hybridized test probes, regardless of the quality of the placement of the oligomer test probes and regardless of the shape of the feature (para 22). Therefore, Kincaid anticipates the claimed invention because Kincaid teaches every limitation of the instant claims.

### ***Conclusion***

#### **10. No claims allowable over the art.**

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.



**Jeanine Goldberg**

**Primary Examiner**

May 31, 2006